Animal Study Proposal

National Institutes of Health -
National Institute of Child Health and Human Development

Leave Blank

Proposal Number _____

Approval Date _____

Expiration Date _____

A. ADMINISTRATIVE DATA:

Principal Investigator _____

Building/Room _____ Telephone _____ FAX _____

Electronic Mail Address _____

Division, Laboratory, or Branch _____

Project Title _____

_____

_____

◯ Initial Submission ◯ Renewal of *Animal Study Proposal* number _____ (complete section D.3.)

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., co-investigators). Attach an *Investigator Training and Experience for Animal Studies* form and proof of Animal Exposure Surveillance Program (AESP) enrollment for each individual.

B. ANIMAL REQUIREMENTS:

Species _____ Age/Weight/Size _____ Sex _____

Stock or Strain _____ Source(s) _____

Holding Location(s) _____ Animal Procedure Location(s) _____

Number of Animals

Year 1	Year 2	Year 3	Total
_____	_____	_____	_____

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies. If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

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D. STUDY OBJECTIVES:

The NICHD Animal Care and Use Committee requires narrative responses for this section in three parts.
Provide these narratives as attachments:

1) NON-TECHNICAL DESCRIPTION OF STUDY OBJECTIVES:
Briefly explain in non-technical terms the aim of the study and how the study may benefit human or animal health or advance scientific understanding of biological processes. The narrative should be approximately 250 words in length with a limit of one page.

2) BACKGROUND AND HYPOTHESIS:
Explain the scientific background and value of the proposed research. Provide a clear statement of the hypothesis or purpose to be accepted or rejected. This information must be provided in addition to the non-technical explanation of the study objectives required in section D.1. The narrative should not exceed two pages in length (not including optional references).

3) RENEWAL ANIMAL STUDY PROPOSALS:
Renewal animal study proposals require an additional attachment to this form that summarizes the progress of the study over the past three years. This narrative should include the following (limit of one page, not including bibliography):

a) The number of animals originally approved by the ACUC and the number of animals actually used for the study.
b) A brief summary of research progress, including a bibliography of publications that have resulted from this work.
c) A brief statement as to why this study should be continued.

E. RATIONALE FOR USE OF ANIMALS:

1) Explain your rationale for animal use.
2) Justify the appropriateness of the species selected.
3) Justify the number of animals to be used.

Provide this narrative as an attachment.

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES:

Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study.
Provide this narrative as an attachment. Specifically address the following:

- Injections or inoculations (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- Blood withdrawals (volume, frequency, withdrawal sites, and methodology)
- Non-survival surgical procedures (Provide details of survival surgical procedures in section G).
- Radiation (dosage and schedule)
- Methods of restraint (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- Animal identification methods (e.g., ear tags, tattoos, collar, cage card, etc.)
- Other procedures (e.g., survival studies, tail biopsies, etc.)
- Resultant effects, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.)
- Experimental endpoint criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation, or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

G. SURVIVAL SURGERY: If proposed, complete the following (use additional sheets if necessary):

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized.

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed? Building/Room _____

4. Describe post-operative care required, including consideration of the use of post-operative analgesics, and identify the responsible individual.

5. Has major surgery been performed on any animal prior to being placed on this study? Y/N ____ If yes, please explain.

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N ____ If yes, please justify.

H. PAIN OR DISTRESS CATEGORY: The ACUC is responsible for applying the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training*, specifically Principle IV which states: "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless the contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Check the appropriate category(ies) and indicate the approximate number of animals in each. Sum(s) should equal total from section B. If animals are indicated in Column E, a scientific justification is required to explain why the use of anesthetics, analgesics, sedatives or tranquilizers during and/or following painful or distressful procedures is contraindicated. Please complete the *Explanation for USDA Column E Listing* form. This form will accompany the NIH annual report to the USDA. This Column E form and any attachments (e.g., the ASP) are subject to the Freedom of Information Act.

		Year 1	Year 2	Year 3
USDA Column C	- Minimal, Transient, or No Pain or Distress	_____	_____	_____
USDA Column D	- Pain or Distress Relieved by Appropriate Measures	_____	_____	_____
USDA Column E	- Unrelieved Pain or Distress	_____	_____	_____

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain and distress to the animals, and your determination that alternatives were not available. [Note: Principal Investigators must certify in section N.5. that no valid alternative was identified to any of the described procedures which may cause more than momentary pain and distress, whether it is relieved or not.] Delineate the methods and sources used in the search. Data base references must include databases searched (2 or more), the date of the search, period covered, and keywords used (provide as an attachment).

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION: For animals indicated in section H, USDA Column D, specify the anesthetics, analgesics, sedatives, or tranquilizers that are to be used. Include the name of the agent(s), dosage, route, and schedule of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If method(s) of euthanasia include those not recommended in the *Report of the AVMA Panel on Euthanasia*, provide justification why such methods must be used. Indicate the method of carcass disposal if not as Medical Pathological Waste.

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an IC safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens are required to be attached.

		LIST AGENTS AND REGISTRATION DOCUMENT NUMBER (IF APPLICABLE)
1. Radionuclides	☐ Yes ☐ No	
2. Biological Agents	☐ Yes ☐ No	
3. Hazardous Chemicals or Drugs	☐ Yes ☐ No	
4. Recombinant DNA	☐ Yes ☐ No	

Study conducted at Animal Biosafety Level _____

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Use of volatile anesthetics requires a description of scavenging methods used. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of radioactivity (use additional sheet if necessary).

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.):

1. Specify Material _____

2. Source _____ Material Sterile or Attenuated? Y/N ____

3. If derived from rodents, has the material been MAP/RAP/HAP tested? Y/N ____ If yes, attach copy of results

4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

_____ **Initials of Principal Investigator**

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY: List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.). Include justification for exemption from participation in the environmental enrichment plan for nonhuman primates or exercise for dogs (use additional sheet if necessary).

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended the NIH course *Using Animals in Intramural Research: Guidelines for Principal Investigators*.

   Year of Course Attendance _____ Year(s) of Refresher Training _____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who have significant animal contact are participating in the NIH Animal Exposure Surveillance Program (AESP). [Attach proof of AESP enrollment for each individual.]
4. I certify that the individuals listed in section A are authorized to conduct procedures involving animals under this proposal and have attended the course *Using Animals in Intramural Research: Guidelines for Animal Users* and will complete refresher training as required. I certify further that they have received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns.
5. FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases (2 or more) as noted in section H, and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I will obtain approval from the ACUC before initiating any significant changes in this study. [Use *Modification to Animal Study Proposal* form.]

Principal Investigator: Signature _____ Date _____

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O. CONCURRENCES: Must be completed before submission to ACUC for review

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a Laboratory or Branch chief.

Name _____ Signature _____ Date _____

Health Physicist (radiation safety) certification of review and concurrence. (Required of all studies utilizing radionuclides.)

Name _____ Signature _____ Date _____

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Comments:

Facility Veterinarian certification of review.

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

P. FINAL APPROVAL:

Certification of review and approval by the NICHD Animal Care and Use Committee and Animal Program Director.

Joseph Mat Schech, D.V.M., APD Signature _____ Date _____

Karl Pfeifer, Ph.D., Chair ACUC Signature _____ Date _____

Safety Representative certification of review and concurrence. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

A. ADMINISTRATIVE DATA (continued):

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., co-investigators). Attach an *Investigator Training and Experience for Animal Studies* form and proof of Animal Exposure Surveillance Program (AESP) enrollment for each individual.

G. SURVIVAL SURGERY (continued):

H. PAIN OR DISTRESS CATEGORY (continued): consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain and distress**:**